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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,844	08/22/2003	Michael R. Duff	31735/70009 CON	8141

23643 7590 01/07/2008  
BARNES & THORNBURG LLP  
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INDIANAPOLIS, IN 46204

EXAMINER
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GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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01/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/645,844	<b>Applicant(s)</b> DUFF ET AL.	
	<b>Examiner</b> Isis A. Ghali	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 41-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ i s/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' response to the office action mailed 06/13/2007.

Claims 41-50 are pending and included in the prosecution.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 1038 and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 41-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furman US 5,451,404('404) in view of JP 06-157327 ('327) and the article "Differences in human evoked potentials related to olfactory or trigeminal chemosensory activation" by Hummel et al.

Furman teaches a coolant composition comprising ketal, menthol and carboxamides, or combination thereof (stimulating organic substances), incorporated into carrier and are suitable for applying or exposure to the skin and/or mucosal membrane in topical compositions that included cleansing tissues i.e. towelette, impregnated with the composition (abstract; col.2, lines 25-51; col.4, lines 38 till col.5, line 45; col.5, lines 60-61; col.6, lines 11-13). The composition is suitable for medical or other reasons and produces the cooling effect when contacts the mucosa or nose or throat by direct or indirect application or inhalation (col.6, lines 1-20). According to the applicants disclosure in page 10, lines 1-8, the stimulating organic substances are the substances that cause a sensation as a result of other sensory mechanism, for example a topical cooling sensation or olfactory sensation, these substances can be utilized as long as the sensation cause a decrease in the drowsiness of the individual.

However, the reference does not explicitly teach such substances reduces drowsiness and does not teach ammonia in the composition.

JP '327 teaches external agent for preventing drowsiness and meanwhile giving excellent feeling in use and having prolonged activity. The external agent comprises menthol and camphor (abstract).

Hummel et al. teaches that ammonia provides nerve stimulation at large amplitude (see the provided abstract).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver tissue impregnated with a stimulating organic substance including menthol or camphor as disclosed by Furman, and use the impregnated tissue to decrease drowsiness as disclosed by JP '327 because JP '327 teaches that menthol and camphor used externally for preventing drowsiness and meanwhile giving excellent feeling in use and having prolonged activity, and one having ordinary skill in the art would have further added ammonia taught by Hummel et al. to the impregnating composition because Hummel teaches ammonia as being able to provide nerve stimulation of large amplitude, with reasonable expectation of having a tissue impregnated with one of ketal, menthol or camphor, and further comprising ammonia that provide nerve stimulation of large amplitude and decrease drowsiness for prolonged time, and meanwhile having excellent feeling on use on the skin.

### ***Response to Arguments***

4. Applicant's arguments filed 10/30/2007 have been fully considered but they are not persuasive.

### **Claims 41-43 and 46**

Applicants argue that no prima facie case of obviousness has been established because JP '327 teaches away from the proposed combination because JP '327

teaches adhesive patch that contact the skin for long time, unlike the wipe that is wiped over the skin quickly and then disposed of.

In response to this argument, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, JP '327 is in the field of applicant's endeavor and reasonably pertinent to the particular problem with which the applicant was concerned. It has been held that the disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). JP '327 is relied upon for the solely teaching of suitability of menthol and camphor for external application on the skin for preventing drowsiness, as desired by applicants. Furthermore, JP '327 teaches advantage of menthol and camphor as they give excellent feeling in use and have prolonged activity, and such teaching would have been motivated one having ordinary skill in the art to use such agents for preventing or treating drowsiness. See KSR Supreme Court of the United State Decision (Decided April 30, 2007, KSR INTERNATIONAL CO. v. TELEFLEX INC, et al. No. 04-1350) where it states that "However, the issue is not whether a person skilled in the art had the motivation to combine electronic control with an adjustable pedal assembly, but whether a person skilled in the art had the motivation to attach electronic control to the support bracket of pedal assembly". In this present case, the product and method of its

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use and method of its making as claimed would have been obvious to one skilled in the art at the time the invention was made because the prior art recognized suitability of the claimed element to prevent or treat drowsiness and also recognized their suitability for application to the skin.

#### **Claims 42-46**

Applicants argue that the cited references do not teach the amount of ammonia as instantly claimed by claims 42-46.

In response to this argument, it is argued that those of ordinary skill in the art would have been readily optimized effective dosages and concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage for treatment of drowsiness involving ammonia would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

#### **Claims 47 and 48**

Applicants argue that the claims depend on claim 41 and are not obvious over the prior art for the same reasons claim 41 is not obvious.

Therefore, the examiner hereby repeats the arguments as set forth in this office action regarding claims 41-43 and 46.

**Claims 49 and 50**

Applicants argue that the claims depend on claim 41 and are not obvious over the prior art for the same reasons claim 41 is not obvious.

Therefore, the examiner hereby repeats the arguments as set forth in this office action regarding claims 41-43 and 46.

Additionally, it is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic  
Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali  
Primary Examiner  
Art Unit 1615

IG

A handwritten signature in cursive script, appearing to read "Isis Ghali".

ISIS GHALI  
PRIMARY EXAMINER